Ivera Medical Corporation
Don Canal
Consultant RA / Qa
2731 Loker Avenue West
Carlsbad, California 92010

March 11, 2022

Re: K110826
Trade/Device Name: Curos Port Protector
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: QBP

Dear Don Canal:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated June 23, 2011 and the correction letter dated December 14, 2018. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under regulation 880.5440.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Payal Patel, OHT3: Office of GastroRenal, Ob-Gyn, General Hospital and Urology Devices, 240-402-6029, Payal.Patel@fda.hhs.gov.

Sincerely,

Payal Patel
Assistant Director for General Hospital Devices
DHT3C: Division of Drug Delivery and General Hospital Devices and Human Factors
OHT3: Office of GastroRenal, Ob-Gyn, General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

FDA U.S. FOOD & DRUG ADMINISTRATION

December 14, 2018

Ivera Medical
Don Canal
RA / QA
2731 Loker Avenue West
Carlsbad, California 92010

Re: K110826
Trade/Device Name: Curos Port Protector
Regulatory Class: Unclassified
Product Code: QBP
Dated: March 18, 2011
Received: March 24, 2011

Dear Don Canal:

This letter corrects our substantially equivalent letter of June 23, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

4. Indications for Use Statement

Device Name: The CUROS™ Port Protector

Indications For Use:

The Curos™ Port Protector is a device containing 70% Isopropyl alcohol. When left in place for 5 to 15 minutes the Curos™ Port Protector decontaminates the injection port; thereafter the Curos™ Port Protector provides a physical barrier during the intended use.

Prescription Use___☑___ **AND/OR Over-The-Counter Use**_____

(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K110826

JUN 2 3 2011

K110826

5. **510(k) Summary**

General Company Information

Name: Ivera Medical Corporation
Contact: Don Canal
Consultant RAQA

Address: Ivera Medical Corporation
3525 Del Mar Heights Road
Suite #430
San Diego, CA 92130

Telephone: 760-612-6090
Fax: 858-228-1770

Date Prepared: May 19, 2011

General Device Description

The **Curos**™ Port Protector device is a single use, sterile device that contains 70% Isopropyl Alcohol and is intended to be used as a disinfectant for needleless luer activated valves.

Common Name: **Pad, Alcohol**
Trade Name: **Curos**™ Port Protector
Classification: Unclassified Device, product Code LKB

Predicate Devices

K080466 Curos Port Protector

Intended Use (Indications)

The Ivera Medical Curos™ Port Protector is a device containing 70% Isopropyl Alcohol. When left in place for 5 to 15 minutes the Curos Port Protector decontaminates the injection port; thereafter, the Curos Port Protector provides a physical barrier during the intended use.

Comparison with Predicate Device

The only change from the predicate device is that the Subject device is provided sterile with the revised labeling to add the sterile symbol. The materials of construction and technological characteristics are the same as the predicate device.

Substantial Equivalence Performance Testing

Ivera medical has provided non-clinical performance test data that demonstrates the pre-defined acceptance criteria for a disinfecting device has been met. This acceptance criteria is defined as a bacteria count reduction of $\geq$ 4 log reduction of 2 selected gram

positive bacteria and 2 selected gram negative bacteria for a period of time from 3 minutes up to 168 hours (7 days). The efficacy testing was completed using a total of 4 bacteria, 2-gram negative and 2 gram positive as recommended in Draft Guidance for Industry and FDA Staff Premarket Notification [510(k)] Submissions for Medical Devices that Include Antimicrobial Agents DRAFT GUIDANCE. This guidance document is being distributed for comment purposes only. Document issued on: July 19, 2007. The bacteria tested and the test results are included in Table 1.

Table 1 - Efficacy Test Results

Organism	Acceptance Criteria (bacterial count reduction (ΔLog))	3 minute exposure (bacterial count reduction (ΔLog))	7 day (168 hours) exposure (bacterial count reduction (ΔLog))
Staphylococcus aureus	≥ 4.0	6.0	6.9
Staphylococcus epidermis	≥ 4.0	6.8	7.3
Escherichia coli	≥ 4.0	5.2	5.2
Pseudomonas aeruginosa	≥ 4.0	5.1	5.1

The data presented demonstrates demonstrate the Subject Device is safe and effective. and the performance test results meet the requirements of its pre-defined acceptance criteria and intended uses.

The Ivera Curos Port Protector is sterilized using a validated Gamma sterilization process which complies with ISO11137-1:2006/(R) Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose. Recognition number 14-225.

ISO11137-2:2006 Sterilization of health care products – Radiation – Part 1: requirements for development of validation and routine control of sterilization process for medical devices. Recognition number 14-297.

11137-3:2006/(R) 2010 10/04/2010 AAMI ANSI ISO 14-298 - Radiation - Part 3: Guidance on Dosimetric Aspects. Recognition number 14-298.FDA recognized standard ISO11137 Sterilization Standard.

Ivera Medical has completed testing to demonstrate the Curos Port Protector materials of construction meet FDA recognized standard ISO10993 for biocompatibility.

Conclusions

The analysis arguments and test results demonstrate the **Curos™** device is substantially equivalent to the predicate devices.